

K070122

510(k) Summary
as required by 807.92

FEB 8 2007

1. Company Identification

EIZO NANA CORPORATION

153 Shimokashiwano-cho, Hakusan, Ishikawa-ken, 924-8566, Japan

Tel: +81-76-274-2468

Fax: +81-76-274-2484

2. Official Correspondent

Hiroaki Hashimoto (Mr.)

Manager of Engineering Management Section

3. Date of Submission

January 9, 2007

4. Device Trade name

Monochrome LCD Monitor, RadiForce GX320

5. Common/Usual Name

Image display system, medical image workstation, image monitor/display, and others

6. Classification Number

Medical displays classified in Class II per 21 CFR 892.2050.

7. Predicate Device

Manufacturer : EIZO NANA CORPORATION

Device Name : Monochrome LCD Monitor

Model Name : RadiForce GS320

510(k) No. : K062053

8. Description of Device

RadiForce GX320 is a 54cm (21.3") Monochrome LCD display for medical image viewing. GX320 displays high-definition medical imaging.

9. Intended Use

RadiForce GX320 is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. The device is not specified for digital mammography system.

10. Technological Characteristics

RadiForce GX320 is substantially equivalent to GS320 (E062053). Additional product innovations include Digital Uniformity Equalizer (DUE), which enables compensates for luminance non-uniformity. The built-in swing calibration sensor and the Protection Panel are equipped with GX320 as standard feature. Comparison table of the principal characteristics of 2 devices in Attachment 1 shows that new and predicate devices are substantially equivalent in the areas of technical characteristics, general functions. Regarding to upgrade in software, refer to Software Information for RadiCX ver.2.5 used for built-in swing calibration sensor. The device does not come into contact with the patient. It does not control any life-sustaining device either. Any difference between both devices not affects safety or efficacy.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Hiroaki Hashimoto
Manager
EIZO NANA Corporation
Engineering Management Section
153 Shimokashiwano-cho
Hakusan, Ishikawa-ken 924-8566
JAPAN

FEB 8 2007

Re: K070122

Trade/Device Name: Monochrome LCD Monitor, RadiForce GX320
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 9, 2007
Received: January 16, 2007

Dear Mr. Hishimoto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

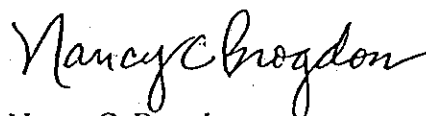
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|----------------|----------------------------------|--------------|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~Not known~~ K070122

Device Name : Monochrome LCD Monitor, RadiForce GX320

Indications For Use:

RadiForce GX320 is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. The device is not specified for digital mammography system.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David B. Legman
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070122